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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/099,926	03/14/2002	Gordon E. King	210121.547C2	3953

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EXAMINER	
RAWLINGS, STEPHEN L	
ART UNIT	**PAPER NUMBER**
1643	

DATE MAILED: 09/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/099,926	KING ET AL.	
	Examiner	Art Unit	
	Stephen L. Rawlings, Ph.D.	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) *1-8,10,11 and 14-17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9,12 and 13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date ~~20030717~~. 20020617
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The election filed June 13, 2005 is acknowledged and has been entered. Applicant has elected the invention of Group 9680, claims 9, 12, and 13, insofar as the claims are drawn to a drawn to a method for stimulating and/or expanding T cells, stimulating an immune response, or treating or inhibiting the development of cancer, wherein said method comprises contacting T cells with a polynucleotide comprising a polynucleotide sequence that is at least 75% identical to the polynucleotide sequence of SEQ ID NO: 1660, the complement thereof, a fragment thereof, a degenerate variant thereof, or a nucleic acid that hybridizes to said polynucleotide or wherein said method comprises administering to a patient a composition comprising said polynucleotide.

Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. Claims 1-17 are pending in the application. Claims 1-8, 10, 11, and 14-17 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

3. Claims 9, 12, and 13 are under prosecution.

Priority

4. Applicant's claim under 35 USC § 120 for benefit of the earlier filing date of U.S. Application Serial No. 10/033,528, filed December 26, 2001, which claims benefit of U.S. Application Serial No. 09/920,300, filed July 31, 2001, which claims benefit of U.S. Provisional Application Serial Nos. 60/223,283, filed August 3, 2000, 60/279,763, filed March 28, 2001, and 60302,051, filed June 29, 2001, is acknowledged.

However, claims 9, 12, and 13 do not properly benefit under 35 U.S.C. § 120 by the earlier filing date of U.S. Provisional Application Serial No. 60/223,283, filed August

3, 2000, since that application does not teach the nucleotide sequence set forth in the instant application as SEQ ID NO: 1660.

To receive benefit of the earlier filing date under 35 USC §120, the later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

Accordingly, the effective filing date of the claims is deemed the filing date of U.S. Provisional Application Serial No. 60/279,763, namely March 28, 2001.

Information Disclosure Statement

5. The information disclosure filed June 17, 2002 has been considered. An initialed copy is enclosed.

Specification

6. The specification is objected to because the use of improperly demarcated trademarks has been noted in this application. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner that might adversely affect their validity as trademarks. See MPEP § 608.01(v).

Examples of such improperly demarcated trademarks include Electromax™ (page 246, line 28) and GenBank™ (page 247, line 7).

Appropriate correction is required. Each letter of a trademark should be capitalized or otherwise the trademark should be demarcated with the appropriate symbol indicating its proprietary nature (e.g., ™, ®), and accompanied by generic terminology. Applicants may identify trademarks using the "Trademark" search engine

under "USPTO Search Collections" on the Internet at http://www.uspto.gov/web/menu/search.html.

Claim Objections

7. Claims 9, 12, and 13 are objected to as being drawn in the alternative to the subject matter of non-elected inventions. Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 9, 12, and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 9, 12, and 13 are indefinite because the claim depend from claim 1 and are thus directed to a genus of polynucleotides that hybridize to a sequence provided by SEQ ID NO: 1660 "under moderately stringent conditions". The specification provides an example of such conditions but discloses the conditions used in practicing the claimed invention can be varied. Thus, the specification does not provide a standard for ascertaining the requisite degree of stringency that must be used in practicing the claimed invention. Accordingly, the moderately stringent hybridization conditions used in practicing the claimed method can vary, such that those conditions might be highly permissive (e.g., conditions under which even very dissimilar nucleic acid molecules remain hybridized) or highly selective (e.g., conditions under which only fully complementary nucleic acid molecules remain hybridized). Depending upon the "moderately stringent conditions" used, the metes and bounds of the subject matter that Applicant regards as the invention will vary; accordingly, claims 9, 12, and 13 fail to delineate the metes and bounds of the subject matter that Applicant regards as the invention with the requisite particularity and clarity, since it is not possible to determine what subject matter does or does not infringe the claimed invention.

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 9, 12, and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This is a "written description" rejection.

The considerations that are made in determining whether a claimed invention is supported by an adequate written description are outlined by the published Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, para. 1, ``Written Description" Requirement (Federal Register; Vol. 66, No. 4, January 5, 2001). A copy of this publication can be viewed or acquired on the Internet at the following address: <http://www.gpoaccess.gov/>.

Claims 9, 12, and 13 are directed to a broad genus of polynucleotides that vary substantially in both structure and function. For example, the genus of polynucleotides includes any polynucleotide that is capable of hybridizing to the polynucleotide of SEQ ID NO: 1660 under moderately stringent conditions. Accordingly, the members of the genus of polynucleotides to which the claims are directed vary substantially in structure. In fact, given the broadest, reasonable interpretation, the claims are directed to a genus of polynucleotides that are at least 75% identical to any two contiguous residues of the polynucleotide sequence provided by SEQ ID NO: 1660, since the specification defines "a" as a plurality and the claims are specifically directed to polynucleotides comprising a sequence having at least 75% identity to a sequence of SEQ ID NO: 1660. Although the intended purpose of the claimed invention is to stimulate and/or expand T cells specific for a tumor protein or to treat cancer in a patient, the claims are directed to

methods comprising contacting T cells with a polynucleotide that varies substantially in structure and does not necessarily encode any one protein, which has any particular function.

Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, paragraph 1, ``Written Description'' Requirement (66 FR 1099-1111, January 5, 2001) states, "[p]ossession may be shown in a variety of ways including description of an actual reduction to practice, or by showing the invention was 'ready for patenting' such as by disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention" (*Id.* at 1104). "Guidelines" further states, "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species *cannot* be achieved by disclosing only one species within the genus" (Id. at 1106); accordingly, it follows that an adequate written description of a genus cannot be achieved in the absence of a disclosure of at least one species within the genus. Because the claims encompass a genus of variant species, an adequate written description of the claimed invention must include sufficient description of at least a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics sufficient to show that Applicant was in possession of the claimed genus. However, factual evidence of an actual reduction to practice has not been disclosed by Applicant in the specification; nor has Applicant shown the invention was "ready for patenting" by disclosure of drawings or structural chemical formulas that show that the invention was complete; nor has Applicant described distinguishing identifying characteristics sufficient to show that Applicant had possession of the claimed invention at the time the application was filed.

The specification provides an adequate written description of the claimed invention only insofar as the claims are directed to a nucleic acid molecule that comprises the polynucleotide sequence set forth as SEQ ID NO: 1660, a nucleic acid molecule that comprises or consists of the *full* complement of the nucleotide sequence set forth as SEQ ID NO: 1660, a nucleic acid molecule that *consists* of a fragment of the

polynucleotide sequence of SEQ ID NO: 1660, and a nucleic acid molecule that *consists* of a polynucleotide sequence that is fully complementary to a fragment of the nucleotide sequence set forth as SEQ ID NO: 1660.

However, the description of these few members of the claimed genus of nucleic acid molecules is not sufficient to meet the requirements of 35 USC § 112, first paragraph, since as explained the genus embraces widely variant members and an adequate description of such cannot be achieved by describing members, which are not representative of the genus. As disclosed and claimed, the genus of nucleic acid molecules does not comprise members having a common, particularly identifying structural feature that correlates with a common functional feature shared by at least a substantial number of its members. As such, absent any of the factual evidence of an actual reduction to practice discussed above, the skilled artisan could not immediately envision, recognize, or distinguish at least a substantial number of the members of the claimed genus said at least substantial number. Accordingly, the specification would not reasonably convey to the skilled artisan that Applicant had possession of the claimed invention at the time the application was filed.

In addition, it is aptly noted that claims 9, 12, and 13 are directed to "degenerate variants" of a sequence provided in SEQ ID NO: 1660. A degenerate variant is a polynucleotide that encodes a polypeptide having an amino acid sequence that is identical to that of a polypeptide encoded by another polynucleotide despite difference in the polynucleotide sequences of the respective polynucleotides due to the well-recognized degeneracy of the genetic code. However, because the specification does not describe the amino acid sequence that is encoded by a sequence provided in SEQ ID NO: 1660, or the open-reading-frame encoding such amino acid sequence, the degenerate variants to which the claims are directed have not been described to an extent that would enable the skilled artisan to immediately envision, recognize or distinguish at least a substantial number of the members of the genus of polynucleotides that are degenerate variants of a sequence provided in SEQ ID NO: 1660.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 9, 12, and 13 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,623,923 B1.

The applied reference has a common assignee and a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

U.S. Patent No. 6,623,923 B1 teaches a method for stimulating or expanding T cells specific for a tumor protein comprising administering to a patient or contacting T cells with a composition comprising a nucleic acid molecule comprising a polynucleotide sequence that is a fragment of SEQ ID NO: 1660, and comprises a polynucleotide sequence that is at least 90% identical to the polynucleotide sequence of SEQ ID NO: 1660, which is therefore reasonably deemed capable of hybridizing to the nucleic acid molecule of SEQ ID NO: 1660 under moderately stringent conditions, and, absent a showing of any difference; see entire document (e.g., the abstract; paragraphs [0017]-[0032], [0184], [1132]-1155]; and SEQ ID NO: 146).

Double Patenting

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 9, 12, and 13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9, 12, and 13 of copending Application No. 10/961,257. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed inventions are so substantially similar that for the most part, the claimed subject matter of the copending application anticipates the claimed subject matter of the instant application and any minor differences in the subject matter claimed in the instant application would be seen as an obvious variation of the subject matter claimed in the copending application. Moreover, to the extent that the instant claims are directed to the elected invention, the copending claims are anticipatory.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

16. Claims 9, 12, and 13 are directed to an invention not patentably distinct from claims 9, 12, and 13 of commonly assigned 10/961,257. Specifically, although the conflicting claims are not identical, they are not patentably distinct from each other for the reasons set forth in the provisional obviousness-type double patenting rejection of claims 9, 12, and 13 in the section above.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned 10/961,257, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee is required under 35 U.S.C. 103(c) and 37 CFR 1.78(c) to either show that the conflicting inventions were commonly owned at the time the invention in this application was made or to name the prior inventor of the conflicting subject matter. Failure to comply with this requirement will result in a holding of abandonment of the application.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

Conclusion

17. No claim is allowed.

18. The prior art made of record and not relied upon is considered pertinent to Applicant's disclosure. U.S. Patent Application Publication Serial No. 2002/0110547 A1 teaches a method for stimulating or expanding T cells specific for a tumor protein comprising administering to a patient or contacting T cells with a composition comprising a nucleic acid molecule comprising a polynucleotide sequence that is a

fragment of SEQ ID NO: 1660 or which is at least 90% identical to the polynucleotide sequence of SEQ ID NO: 1660.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen L. Rawlings, Ph.D. whose telephone number is (571) 272-0836. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Stephen L. Rawlings, Ph.D.
Examiner
Art Unit 1643

slr
August 30, 2005